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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

DORNBUSCH, DIANNE

ART UNIT	PAPER NUMBER
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3773

NOTIFICATION DATE	DELIVERY MODE
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03/20/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No. 10/584,968	Applicant(s) KAPLAN ET AL.	
	Examiner DIANNE DORNBUSCH	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-24,36-44,47 and 49-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-24,36-44,47 and 49-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/20/08, 1/05/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. For examination purposes, "frond" is being interpreted as being any extension that is protruding from the proximal or distal portion of the stent. Additionally, the frond is a segment which can be between two rings at the distal or proximal portion of the stent.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 5, 2009 has been entered.

Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claim 36 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is

proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 14-24, 36-44, 47, and 49-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 14 has the newly added limitation that the side wall openings in between adjacent fronds are sized and configured to receive a stent deployment device. This is new matter since the side walls openings of the fronds in the original disclosure does not receive the stent deployment device.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 14-16, 21, 22, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. (2004/0254627).

Thompson discloses the following claimed limitations:

Claims 14 and 36: A prosthesis (120) for placement at an opening from a main body lumen to a branch body lumen, the prosthesis comprising: a radially expansible support (22), the support configured to be deployed in at least a portion of the branch body lumen, the support adapted to provide a first radial force to support the body lumen (once deployed in the vessel it exerts a radial force against the vessel wall); at least two elongate, flexible fronds (a pair of parts 32) each having a first end, a second end and an axially extending undulating elongate portions having a plurality of crests and troughs between the first and second ends (Fig. 13), at least a portion of the elongate portion comprising a plurality of spaced apart filaments (32) having crests and troughs extending in phase (Fig. 13), the fronds extending from an end of the support and configured to be positioned across the Os and into the main body lumen (Fig. 13); and at least one circumferential link (130) comprising an undulating pattern including a plurality of crests and troughs (Fig. 13), the circumferential link spaced axially apart from the support by the fronds (Fig. 13) and adapted to provide a second radial force that is less than the first radial force (when deployed the link will have a second radial force and due to a smaller size of the part it will be lower than the first radial force); and a plurality of elongate side wall openings in between adjacent fronds (Fig. 13) sized and configured to receive a stent deployment device therethrough; and the elongate, flexible fronds, the support and the circumferential link defining a unitary body as deployed (Fig. 13), the elongate side wall openings in between adjacent fronds (the gaps between each frond seen in Fig. 13) for facilitating crossing of a main vessel stent therethrough

when the support is positioned in the branch body lumen and the circumferential link is positioned in the main body lumen.

Regarding the statements with respect to the side wall openings function, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

With respect to the adapted to statements, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Thompson discloses the claimed invention except for the fronds being connected to the crests of the circumferential link instead of the troughs. It would have been obvious to one having ordinary skill in the art at the time the invention was made to connect the end of the fronds to the crest instead of the troughs of the circumferential link, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Claim 15: The circumferential link comprises an undulating pattern having at least three apexes (the link contains an undulating pattern with more than three apexes as seen in Fig. 13).

Claim 16: Comprising three fronds (Fig. 13).

Claims 21 and 22: Thompson discloses that the end of the struts are radiopaque (claim 22) and that the fronds are made of tantalum which is a radiopaque material ([0028] last three lines) as well as the fronds having a higher radiopacity than the rest of the device which can be seen in Fig. 13 due to the thickness of the device. However, Thompson does not specify that the link is radiopaque nor that the link has higher radiopacity than the fronds.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the link radiopaque, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70. Furthermore it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the link out of tantalum which is radiopaque, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

9. Claims 14-18, 23, 24, 36, 43, 44, and 47 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jayaraman (5,755,781) in view of Killion et al. (6,485,509).

Claim 14:

Jayaraman discloses a prosthesis (70) for placement at an opening from a main body lumen to a branch body lumen, the prosthesis comprising: a radially expansible support (see figure below), the support configured to be deployed in at least a portion of the branch body lumen, the support adapted to provide a first radial force to support the

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body lumen (once deployed in the vessel it exerts a radial force against the vessel wall); at least two elongate, flexible fronds (see figure below) each having a first end, a second end and an axially extending undulating elongate portions having a plurality of crests and troughs between the first and second ends (see figure below), at least a portion of the elongate portion comprising a plurality of spaced apart filaments (71) having crests and troughs extending in phase (see figure below), the fronds extending from an end of the support and configured to be positioned across the Os and into the main body lumen (see figure below); and at least one circumferential link (see figure below) comprising an undulating pattern including a plurality of crests and troughs (see figure below), the circumferential link being connected at crests thereof to the second ends of the fronds (see figure below), the circumferential link spaced axially apart from the support by the fronds (see figure below); and a plurality of elongate side wall openings in between adjacent fronds (the gaps between each frond seen in the figure below) sized and configured to receive a stent deployment device therethrough; and the elongate, flexible fronds, the support and the circumferential link defining a unitary body as deployed (Fig. 9 and 28), the elongate side wall openings in between adjacent fronds (the gaps between each frond seen in the figure below) for facilitating crossing of a main vessel stent therethrough when the support is positioned in the branch body lumen and the circumferential link is positioned in the main body lumen.

Regarding the statements with respect to the side wall openings function, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art

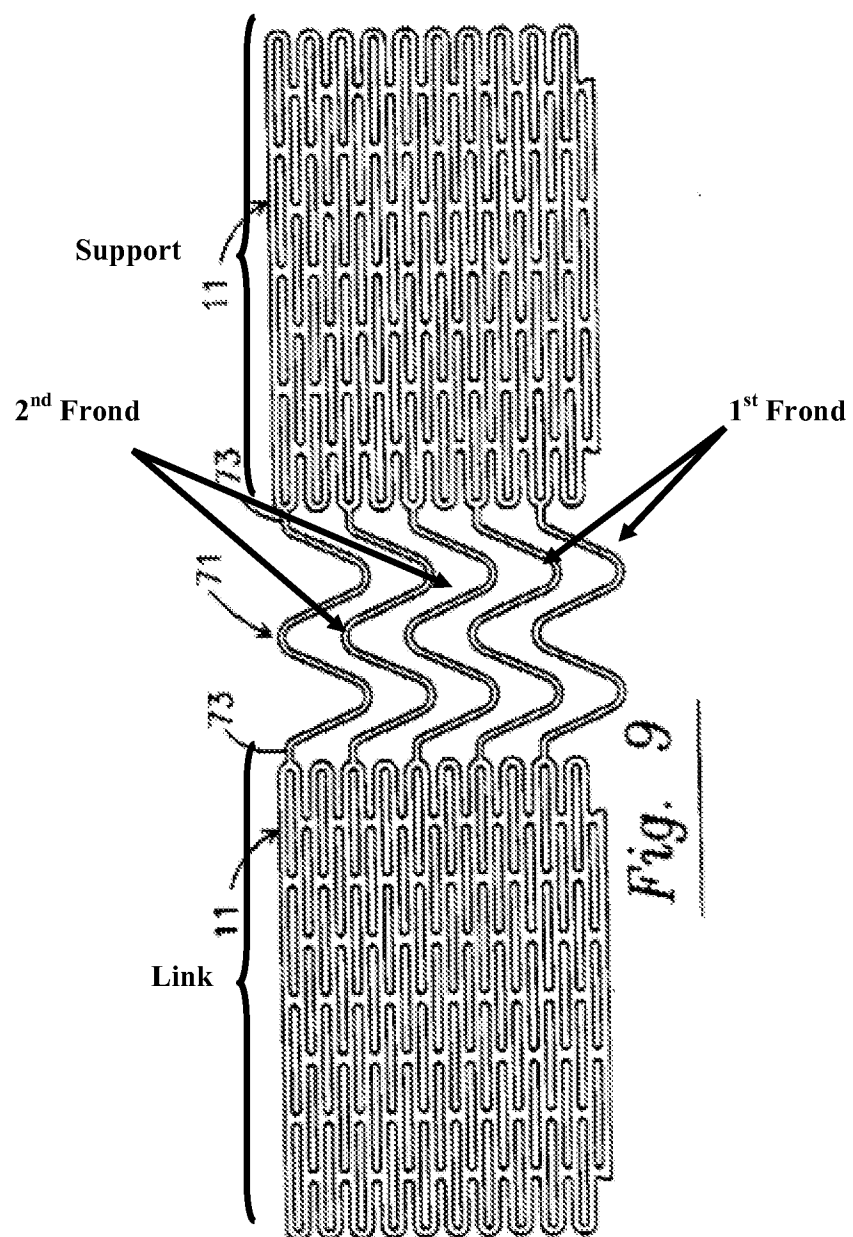
apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

With respect to the adapted to statements, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. Specifically, regarding the statement that the circumferential link is adapted to provide a second radial force that is less than the first radial force. The device of Jayaraman does have a radial force caused by the circumferential link on the vessel. The circumferential link could be adapted to have a lower radial force than the first radial force in the case where the device is inserted into a bifurcated vessel where one portion has a smaller diameter than the other which would cause the circumferential link to have a lower radial force on the vessel when inserted in the smaller portion.

Furthermore, it would have been obvious to have a device such as the device of Jayaraman to have variable radial force in view of the teachings of Killion.

Killion discloses a stent which has varying radial force along the length of the vessel (Abstract, Col. 2 Lines 63-65, and Col. 3 Lines 1-10 and 23-25). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Jayaraman with the circumferential link having a smaller radial force than the support in view of the teachings of Killion, in order provide the necessary force against healthy, non-stenosed vessel while the support maintains the stenosed area open (Col. 2 Lines 29-34).

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Claim 15: The circumferential link comprises an undulating pattern having at least three apexes (the link contains an undulating pattern with more than three apexes as seen in the figure above).

Claim 16: Comprising three fronds (Fig. 9).

Claim 17: At least one frond comprises a helical configuration (Fig. 9 where the fronds have a spiral/helical shape).

Claim 18: A plurality of helical fronds (Fig. 9).

Claim 23: The prosthesis comprising an endothelial cell ingrowth surface (Fig. 9). The surface is capable of promoting cell ingrowth.

Claim 24: The prosthesis comprising a non thrombogenic surface (Col. 6 Lines 35-37).

Claim 36: At least one frond comprises a plurality of parallel, undulating filaments (see figure above).

Claim 43: That the circumferential link comprises a single transverse filament (see figure above where the link is made from a single material that is laser cut (Col. 4 Lines 10-20).

Claim 44: Comprising a transition section (73) between the support and the fronds (see figure above).

Claim 47: That the prosthesis includes a drug incorporated into a polymer matrix (Col. 4 Lines 30-32).

10. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jayaraman (5,755,781) in view of Killion et al. (6,485,509) and further in view of Summers et al. (5,342,387).

Jayaraman all the claimed limitations discussed above including that the device contains a coating (Col. 4 Lines 23-25) however, Jayaraman does not disclose a lubricous coating.

Summer discloses that at least a portion of the at least one frond comprises a lubricous coating (Col. 4 Lines 27-30). The surface of the stent (this includes the fronds) is coated with a gel coating which causes the surface to be smooth (Col. 4 Lines 36-40).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Jayaraman and Killion with a lubricous coating in view of the teachings of Summer, in order to have a smooth surface to avoid abrasions on the vessel wall.

11. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jayaraman (5,755,781) in view of Killion et al. (6,485,509).

Jayaraman discloses the claimed invention except for the axial length of the fronds being at least 8mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the length of the fronds at least 8mm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

12. Claims 21, 22, 37-41, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jayaraman (5,755,781) in view of Killion et al. (6,485,509) and further in view of Callol et al. (2002/0183763).

Claims 21 and 22:

Jayaraman and Killion discloses all the claimed limitations discussed except for the circumferential link being radiopaque.

Callol discloses a prosthesis with a radially expansible support (26), the support configured to be deployed in at least a portion of the branch body lumen ([0140] last sentence); at least two elongate, flexible frond (39 where each frond is each portion that extends from the support 26 to the peak) each having a first end (the portion connected to the support (26)), a second end (the end of the peaks which connects to portion (29)), and a length between; and at least one circumferential link (proximal portion of 29) connected to the second end of the fronds (39).

Additionally Callol discloses the following claimed invention:

Claim 21: That the circumferential link is radiopaque ([0148] first sentence). The link is made from a ring (30) and strut (31) which can have variable thicknesses that provide higher radiopacity therefore they are radiopaque.

Claim 22: That the circumferential link has a greater radiopacity than the frond. The radiopacity of the link as disclosed in paragraph [0152] varies depending on the thickness of the ring (30) and the strut (31) therefore the link is capable of having higher radiopacity than the frond. Furthermore, the frond (39) is not radiopaque which indicates that the link will have higher radiopacity than the frond.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Jayaraman and Killion with the circumferential link

being radiopaque in view of the teachings of Callol, in order to be able to see the link as it is being delivered to the desired vessel position.

Claims 37-41 and 49:

Jayaraman and Killion discloses all the claimed limitations discussed except for a drug coating.

Callol discloses the following claimed limitations:

Claim 37: That at least a portion of the radially expansible support (26) comprises a drug coating ([0150] Lines 1-2), and at least a portion of the fronds (39) and the circumferential link (29) are without a drug coating (Claim 20). It is disclosed that the device can be coated completely or only portions which indicates that the fronds and link are not coated.

Claim 38: That the drug coating is configured to produce a controlled drug release rate ([0150] Lines 9-11).

Claim 39: That the drug is one of an anti-cell proliferative ([0150] Lines 18-19), anti cell migration, anti-neo plastic, anti inflammatory drug ([0150]).

Claim 40: That the drug is configured to reduce restenosis ([0150] Lines 1-4).

Claim 41: That the drug coating includes a first coating and a second coating ([0150] Lines 4-11).

Claim 49: That the polymer includes a base layer and a top layer (a first and second coating), the drug being incorporated into at least one of the top layer and the base layer ([0150] Lines 4-11)

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Jayaraman and Killion with a drug coating in view of the teachings of Callol, in order to assist in repair of the vessel and may be useful, for example, in reducing the likelihood of the development of restenosis ([0152]).

13. Claims 42, 50, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jayaraman (5,755,781) in view of Killion et al. (6,485,509) and further in view of Callol et al. (2002/0183763) and Jang (2004/0106985).

Claim 42:

Jayaraman and Killion in view of Callol teaches all the claimed limitations discussed above however, Jayaraman and Killion in view of Callol does not disclose that the first coating is configured to produce a first drug release rate and the second coating is configured to produce a second drug release rate.

Jang discloses that the first coating is configured to produce a first drug release rate and the second coating is configured to produce a second drug release rate ([0351]).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Jayaraman and Killion in view of Callol with different release rates for the drug coatings in view of the teachings of Jang, in order to control the amount of drug that is released as well as to better enable safe encapsulation of the implanted stent.

Claims 50 and 51:

Jayaraman and Killion in view of Callol teaches all the claimed limitations discussed above however, Jayaraman and Killion in view of Callol does not disclose that the prosthesis includes one or more reservoirs configured to be loaded with one or more drugs.

Jang discloses that the prosthesis includes one or more reservoirs (27) configured to be loaded with one or more drugs ([0352] first sentence).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Jayaraman and Killion in view of Callol with reservoirs for loading one or more drugs in view of the teachings of Jang, in order to facilitate the retention and delivery of the drugs.

Response to Arguments

14. Applicant's arguments filed November 17, 2008 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./

Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773